IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION MDL No. 2187

THIS DOCUMENT RELATES TO C. R. BARD WAVE 4 & WAVE 5 CASES

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Charbel Salamon, M.D.)

Pending in *In re C. R. Bard, Inc. 2:10-md-2187*, MDL 2187, is the plaintiffs' *Daubert* motion to Exclude Certain Opinions and Testimony of Charbel Salamon, M.D. [ECF No. 4573]. The motion is now ripe for consideration because the briefing is complete. As set forth below, the plaintiffs' motion is **GRANTED in part**, **DENIED is part**, and **RESERVED in part**.

I. Background

These groups of cases reside in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 29,000 cases currently pending, approximately 3,000 of which are in the C. R. Bard, Inc. MDL, MDL No. 2187.

In an effort to manage the massive Bard MDL efficiently and effectively, the court decided to conduct pretrial discovery and motions practice on an individualized

basis. To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, I enter a docket control order subjecting each active case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order ("PTO") # 236, *In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:10-md-02187, Jan. 27, 2017, https://www.wvsd.uscourts.gov/MDL/2187/orders.html. Included among the discovery rules imposed by the court is the obligation of the parties to file *Daubert* motions seeking to limit or exclude the testimony of general experts in the main MDL, MDL 2187, and to identify which cases the motion would affect.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods" which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. However, he or she must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court is the gatekeeper. It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading"; the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I "need not determine that the proffered expert testimony is irrefutable or certainly correct" – "[a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (quoting *Daubert*, 509 U.S. at 596 (alteration in original)); *see also Md. Cas. Co.*, 137 F.3d at 783 ("All *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful.").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" (citation omitted)); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

III. Analysis

Bard offers Dr. Charbel Salamon as an expert in the area of urogynecology. The plaintiffs seek to preclude seven different opinions advanced by Dr. Salamon; specifically, that: (1) the Align mesh was optimally designed to prevent foreign body reaction; (2) Bard was not required to perform premarket clinical trials on the Align; (3) polypropylene mesh midurethral slings are the worldwide standard in treating

stress urinary incontinence ("SUI"); (4) the Align Instructions for Use ("IFU") provide safe guidelines for using the Align implant; (5) polypropylene is safe for permanent implantation in the human body; (6) the Align mesh does not shrink or degrade after being implanted; and (7) FDA orders relating to pre-market approval of mesh devices for transvaginal prolapse repair do not apply to mesh devices used for abdominal prolapse repair or treatment of SUI.

As discussed below, the plaintiffs' motion to exclude certain opinions expressed by Dr. Salamon is **GRANTED in part, DENIED in part, and RESERVED in part**.

1. The Design of the Align Products

According to the plaintiffs, Dr. Salamon rests his conclusion that the Align products are safe entirely upon his blank assertion that the Align products are similar to the Avaulta products, which he also identifies as safe. In moving to exclude Dr. Salamon's opinion concerning the safety and efficacy of the Align products, the plaintiffs argue that Dr. Salamon failed to substantiate his claim that the Align products are comparable to the Avaulta products, or cite studies that support his claim that the Align or Avaulta devices are safe and effective.

In response, Bard contends that Dr. Salamon adequately correlates the Align products to the Avaulta products. Indeed, Dr. Salamon reports that the Align and Avaulta products are made of the same material and share a common pattern. Dr. Salamon's report also includes citations to characteristics of the Align products that "make it 'safe, effective, and reliable'"; several studies on the Avaulta products; and a report titled "The Align Urethral Support System for the Surgical Management of

Stress Urinary Incontinence in Women," which concludes that the Align product is "highly effective" in the management of women with SUI. *See* Bard's Br. in Opp'n to Pls.' Mot. to Exclude Ops. of Charbel Salamon, M.D. at 6-7 [ECF No. 4631].

Here, the plaintiffs do not address the foundation of the articles cited as support in Dr. Salamon's report, or articulate grounds of unreliability beyond their conclusory assertion that Dr. Salamon's opinions lack foundation. The plaintiffs are free to cross-examine Dr. Salamon regarding these studies. The plaintiffs' motion is **DENIED** on this ground.

2. Pre-Market Clinical Trials

Next, the plaintiffs seek the exclusion of Dr. Salamon's opinion that pre-market clinical trials of the Align product were not necessary. According to the plaintiff, Dr. Salamon's opinion lacks a reliable foundation. In response, Bard represents that Dr. Salamon's conclusions are based on: "(1) the extensive body of literature demonstrating midurethral slings to be safe and effective and (2) the fact that the type of mesh that was . . . considered the most appropriate material for the surgical treatment of prolapse and SUI was used to make the Avaulta and Align." *Id.* at 9 (citations omitted).[1]

In support of their positions, both parties cite my opinion *Eghnayem v. Boston Scientific Corp.*, 57 F.Supp.3d 658 (S.D. W. Va. 2014). In *Eghnayem*, I acknowledged that an expert report backed by relevant authoritative studies is "more than a bare

[1] Bard also notes that the FDA's 510(k) submission process did not require randomized control trials of mid-urethral slings. As I have repeatedly held, the FDA 510(k) clearance process does not speak directly to safety and efficacy.

declaration of [the expert's] professional opinion." *Id.* at 695. Though potentially relevant, Dr. Salamon does not explain how the safety and efficacy of midurethral slings in general, or how the appropriateness of the mesh utilized in these mesh products, have any scientific bearing on the necessity of pre-market clinical trials. In other words, Dr. Salamon fails to correlate his methodology to his conclusion that pre-market clinical trials of the Align product were not necessary. Thus, Dr. Salamon's commentary is nothing more than a bare declaration of his professional opinion. Accordingly, Dr. Salamon's testimony on this point is unreliable under *Daubert* and the plaintiffs' motion is **GRANTED** on this point.

3. Position Statements

The plaintiffs argue that Dr. Salamon relies on the position statements of certain associations to substantiate his opinion that polypropylene mesh midurethral slings are safe and effective. As previously noted by the court, position statements themselves are not expert opinions. *Huskey v. Ethicon, Inc.*, 29 F.Supp.3d 691, 731 (S.D. W. Va. 2014). Bard contends that Dr. Salamon does not rely upon the position statements to support his conclusion, and that his reference to the position statements only reflect the consensus of the medical community.

As I have previously indicated in these MDLs, I will not address the admissibility of such testimony at this time. Accordingly, I **RESERVE** ruling on the admissibility of this testimony for trial. *See, e.g.*, *Flandro v. Bos. Sci. Corp.*, No. 2:13-CV-17027, 2016 WL 3282734, at *14 (S.D. W. Va. June 14, 2016); *Griffin v. Bos. Sci. Corp.*, No. 2:13-CV-11876, 2016 WL 3031700, at *18 (S.D. W. Va. May 25, 2016).

4. Instructions for Use ("IFU")

According to the plaintiffs, Dr. Salamon is not qualified to offer expert testimony on the adequacy of the Align product's IFU because he was not involved in the drafting of the IFU. Bard, in response, argues that Dr. Salamon is qualified because he is the exact type of physician for whom the IFUs are intended and because he has given "feedback" on IFUs created by medical device companies. Bard's Br. in Opp'n to Pls.' Mot. to Exclude Ops. of Charbel Salamon, M.D. at 12 (citing Ex. C, Salamon Dep. 86:10-20).

I **FIND** that without additional expertise in the specific area of product warnings, a doctor, such as an urogynecologist, is not qualified to opine on the adequacy of a product warning IFU merely because it included risks he has observed in his own practice or provided "feedback" previously on IFUs created by medical device companies. Accordingly, the plaintiffs' motion on this point is **GRANTED**.

5. Opinions Regarding the MSDS Sheet

The plaintiffs seek to prevent Dr. Salamon from testifying regarding the utility and interpretation of language contained in the MSDS sheet related to the polypropylene resin in question. In response, Bard states that Dr. Salamon does not intend to offer testimony on the state of mind of the drafter of the MSDS or represent his interpretation of the MSDS. Rather, Bard contends, Dr. Salamon only opines that physicians such as himself do not use MSDSs for raw materials to determine whether finished medical devices are safe.

As it relates to Dr. Salamon's opinion on the utility of the MSDS, a narrative of who uses MSDS in the field is not helpful to the jury. The pertinent issue is that the MSDS contained a warning allegedly not heeded by Bard, not whether practicing physicians regularly consult the warnings. Therefore, the plaintiffs' motion on this point is **GRANTED**.

6. Opinion Regarding Whether the Align Mesh Degrades *in vivo*

The plaintiffs contend that Dr. Salamon's opinion that the mesh does not degrade *in vivo* lacks sufficient reliability and foundation. Specifically, the plaintiffs take issue with Dr. Salamon's reliance on "the Dietz study," while simultaneously ignoring "the Feiner study." The plaintiffs further argue that Dr. Salamon cannot testify that he has "seen no signs of roping or curling of the Align" and that he "believe[s] the pore size, density, and weight of the Align . . . to be appropriate at the time sold because, they claim, such statements are based solely on his personal, unscientific observations as a practicing physician." Memo. in Supp. of Pls. Gen. Mot. to Exclude Certain Ops. & Test. of Charbel Salamon, M.D. at 9 [ECF No. 4575].

In response, Bard represents that the plaintiffs did not question Dr. Salamon about the Feiner study during his deposition; do not cite any contrarian views to Dr. Salamon's statements in the Feiner study; and do not explain the inconsistency of Dr. Salamon's methodology. Regardless, the presentation of a contrary study as a means of discrediting another study cited by an expert, without more, does not prong the reliability of that expert. *See Patteson v. Maloney*, 968 F. Supp. 2d 169, 174-75 (D.D.C. 2013) ("[T]he sole question for the Court is whether [the expert's] studies are

sufficiently reliable under Rule 702 and *Daubert* to be admissible—not whether [the expert's] studies trump [another's].").

However, Bard does not appear to respond directly to the plaintiffs' request to exclude certain statements made by Dr. Salamon. On the one hand, Bard generally defends Dr. Salamon's opinions as based on his extensive clinical experience and a review of the medical and scientific literature, which, in the abstract, are reasonable bases from which to form an expert opinion. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999) ("[N]o one denies that an expert might draw a conclusion from a set of observations based on extensive and specialized experience."). On the other hand, sweeping statements about support within the medical community or medical literature can be difficult to assess.

Although the expert report indicates Dr. Salamon reviewed an extensive list of literature in forming his opinions generally, the court does not have enough information to judge the reliability or relevance of these particular clinical observations or Dr. Salamon's methodology in this specific context. As such, I am without sufficient information at this time to draw the fine line between reliable and unreliable expert testimony on physical mesh properties. Accordingly, I **RESERVE** ruling until further testimony may be offered and evaluated firsthand at trial.

7. FDA 510(k) Clearance

As noted above, I have repeatedly excluded evidence regarding the FDA's section 510(k) clearance process in these MDLs. For the same reasons articulated

previously, expert testimony related to the section 510(k) process, including subsequent enforcement actions and discussion of the information Bard did or did not submit in its section 510(k) application, is **EXCLUDED**. Opinions about Bard's compliance with or violation of the FDA's labeling and adverse event reporting regulations are **EXCLUDED**. Insofar as any *Daubert* motion in this case challenges the FDA-related testimony discussed here, the motions are **GRANTED**.

IV. Conclusion

To summarize, I **GRANT in part, DENY in part, and RESERVE in part** the plaintiffs' motion concerning Dr. Charbel Salamon, M.D., M.S., FACOG [ECF No. 4573] consistent with my reasoning above.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2187, and the Bard Wave 4 and Wave 5 cases identified in the Exhibit attached hereto. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: January 23, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

EXHIBIT A

EXHIBIT A

PLAINTIFF	ORIGINAL CAFN	WAVE
Barker, Lorie	2:13-cv-33690	4
Bivens, Geraldine L	2:16-cv-11116	4
Black, Brenda L	2:14-cv-00952	4
Branscome, Christine E	2:16-cv-10995	4
Brewer, Pamela R	2:16-cv-11135	4
Brown, Cathy	2:16-cv-10807	4
Carnahan, Kathy	2:13-cv-24208	4
Cooley, Dedra	2:14-cv-07543	4
Cuffee, Carolyn D	2:14-cv-02528	4
Degarmo, Nora	2:12-cv-07578	4
Drake, Theresa	2:16-cv-03709	4
Edwards, Claudine	2:14-cv-27463	4
Ford, Janet Marie	2:14-cv-09878	4
Gardiner, Gloria	2:13-cv-15209	4
Gilbert, April D	2:16-cv-11118	4
Gritten, Linda M	2:16-cv-03707	4
Guerrero, Angelia	2:14-cv-14209	4
Hall, Cardisa M	2:16-cv-11113	4
Henderson, Teresa	2:16-cv-03779	4
Holmes, Robin	2:13-cv-01524	4
Hummel, Niki	2:13-cv-32359	4
Johnson, Nancy	2:13-cv-19736	4
Jones, Thelma J	2:16-cv-03719	4
Keisling, Linda	2:16-cv-03721	4
Lackey, Danielle R	2:16-cv-11011	4
Landers, Samantha	2:13-cv-26574	4
Ledwein, Judy	2:16-cv-03778	4
Lee, Frankie	2:12-cv-07570	4
Long, Pamela D	2:13-cv-20881	4
Martin, Judy A	2:16-cv-11103	4
Massey, Shannon L.	2:14-cv-01027	4
McWilliams, Brenda K	2:16-cv-11104	4
Miller, Alice F	2:16-cv-11014	4
Moore, Carol	2:16-cv-03842	4
Moore, Carolyn S	2:14-cv-00606	4
Morgan, Khristina S	2:16-cv-11016	4
Nadeau, Susan J	2:16-cv-11112	4
Nall, Stephanie	2:13-cv-01526	4
Newell, Carmen	2:13-cv-16405	4
Phelps, Inna V	2:16-cv-11114	4
Pickering, Hope	2:16-cv-03896	4
Politi-Topal, Kathleen	2:14-cv-01411	4
Powell, Mary C	2:16-cv-11017	4
Powers, Lisa R	2:16-cv-11041	4
Priddy, Judy M	2:13-cv-10318	4

EXHIBIT A

PLAINTIFF	ORIGINAL CAFN	WAVE
Purcell, Kim	2:13-cv-34058	4
Radatz, Mary L.	2:13-cv-17989	4
Raines, Cynthia Ann	2:13-cv-26748	4
Richardson, Cynthia O	2:13-cv-20036	4
Richardson, Demetria	2:12-cv-02564	4
Rodericks, Rhonda K	2:16-cv-11115	4
Rogers, Rosemary J	2:16-cv-11106	4
Sheaffer, Julie A	2:14-cv-05601	4
Silvia, Diane	2:14-cv-25366	4
Smith, Tamela	2:13-cv-30640	4
Speetzen, Michelle	2:13-cv-12416	4
Stapel, Catherine	2:14-cv-25362	4
Stewart, Mary Sue	2:14-cv-27466	4
Stoddard, Sloane	2:14-cv-11940	4
Struble, Maureen	2:16-cv-03817	4
Swiney, Ernestine F	2:16-cv-11021	4
Teeples, Mistie D	2:16-cv-11020	4
Toulson, Patricia	2:16-cv-03816	4
Updike, Melody A	2:16-cv-11035	4
Weber, Erika	2:16-cv-11105	4
Wilson, Elizabeth J	2:14-cv-14119	4
Woodard, Elizabeth E	2:16-cv-11040	4
Alvey, Christine	2:16-cv-07705	5
Bailey, Carla	2:16-cv-06362	5
Barton, Joan	2:16-cv-07655	5
Bess, Joyce	2:16-cv-06318	5
Clarke, Janice	2:16-cv-10809	5
Cole, Jeanene	2:16-cv-07402	5
Collins, Dana	2:16-cv-06739	5
Corley-Davis, Celia	2:16-cv-10811	5
Crook, Julie	2:16-cv-06360	5
Crowe, Karen F	2:16-cv-11136	5
Currie, Arlene	2:16-cv-10814	5
Daily, Catherine T	2:16-cv-11137	5
Davis, Debra M	2:16-cv-11139	5
Dennis, Barbet	2:16-cv-10815	5
Donley, Teresa	2:16-cv-07322	5
Donovan, Thoris L	2:16-cv-11142	5
Ellis, Karen	2:16-cv-07694	5
Elrod, Josephine	2:16-cv-04032	5
Fay, Paula A	2:16-cv-11144	5
Frederick, Cheryl D	2:16-cv-11266	5
Hale-Cuellar, Patricia A	2:16-cv-11150	5
Hauber, Elizabeth A	2:16-cv-11158	5
Herrera, Wynde Lynn	2:16-cv-10819	5

EXHIBIT A

PLAINTIFF	ORIGINAL CAFN	WAVE
Hill, Mignon M	2:16-cv-11161	5
Jasso, Mary	2:16-cv-06361	5
Jeffries, Lynda	2:16-cv-11798	5
Johnson, Elisa J	2:16-cv-11147	5
Josey, Tammy	2:16-cv-11803	5
Knernschield, Peggy	2:16-cv-06743	5
Kolodzyk, Virginia L	2:16-cv-11163	5
Krishnan, Meera	2:16-cv-06740	5
Kyes, Marilyn	2:16-cv-11804	5
Leyba, Lorraine	2:13-cv-16401	5
Lingenfelter, Nancy	2:16-cv-07610	5
Mahnke, Joyce C	2:16-cv-11167	5
Martinez, Tammy	2:16-cv-10821	5
Mathis, Nellie	2:16-cv-08014	5
Miecznikowski, Jennifer	2:16-cv-11169	5
Morrill, June	2:16-cv-11170	5
Nichols, Brandey R	2:16-cv-11186	5
Piper, Connie	2:16-cv-11811	5
Prince, Marjorie	2:16-cv-04949	5
Reynolds, Cassandra	2:16-cv-11175	5
Roberts, Carla	2:16-cv-06741	5
Roberts, Sheila	2:16-cv-05003	5
Smith, Sandra	2:16-cv-11817	5
Stephenson, Erin	2:16-cv-11819	5
Stevens, Terri L	2:16-cv-11820	5
Tatum, Tuesday	2:16-cv-11821	5
Thompson, Reba	2:16-cv-04536	5
Watson, Charlotte	2:16-cv-03989	5
Yoder-Brady, Bobbye	2:16-cv-03954	5
Young, Carolyn	2:16-cv-04037	5